MEDI-CAL UPDATE Part 2
Billing and Policy
www.medi-cal.ca.gov

Medical Services • General Medicine

August 2006 • Bulletin 385

Contents

Clofarabine is a New Medi-Cal Benefit

Effective September 1, 2006, clofarabine is a Medi-Cal benefit, reimbursable with HCPCS code J9027. Code J9027 may be billed in conjunction with CPT-4 code 96412 (chemotherapy administration, intravenous; infusion technique, one to eight hours). Clofarabine is an intravenous drug used in children 1 to 21 years of age for the treatment of relapsed or refractory acute lymphoblastic leukemia, only after at least two other types of treatment have failed.

The updated information is reflected on manual replacement pages chemo 23 (Part 2) and inject list 5 (Part 2).

Topotecan is a New Medi-Cal Benefit

Effective for dates of service on or after September 1, 2006, topotecan (Hycamtin) is a Medi-Cal benefit, reimbursable with HCPCS code J9350. Topotecan is used in the treatment of metastatic carcinoma of the ovary and small cell lung cancer sensitive disease after chemotherapy has failed.

Code J9350 must be used in conjunction with one of the following ICD-9 diagnosis codes:

- Ovarian cancer (183.0 – 183.9, 196.6, 198.6, 236.2, 239.5)
- Small cell lung cancer (162.0 – 162.9, 197.0, 239.1)
- Myeloid leukemia, chronic, without remission (205.10)
- Neoplasm of uncertain behavior of other lymphatic and hematopoietic tissues (238.7)

Topotecan is contraindicated when the following medical conditions exist:

- Bone marrow depression
- Severe renal impairment
- Hypersensitivity reactions to topotecan or any of its ingredients

Note: When a claim is billed using code J9350 and is authorized by the California Children's Services (CCS) program or the Genetically Handicapped Persons Program (GHPP), the diagnosis restrictions above will be overridden.

This information is reflected on manual replacement pages chemo 13 and 14 (Part 2) and inject list 18 (Part 2).

Negative Pressure Wound Therapy Billing Reminder

Providers are reminded that CPT-4 codes 97605 – 97606 (Negative Pressure Wound Therapy [NPWT]) are not Medi-Cal benefits. Reimbursement for services described by these codes is included in the payment for HCPCS code E2402 (NPWT electrical pump).

This information is reflected on manual replacement page medne 9 (Part 2).

2007 ICD-9 Diagnosis Code Update

The following diagnosis code additions, inactivations and revisions are effective for claims with dates of service on or after October 1, 2006. Providers may refer to the *2007 International Classification of Diseases, 9th Revision, Clinical Modifications, 6th Edition* for ICD-9 code descriptors.

Additions
The following ICD-9 diagnosis codes are new:

052.2	053.14	054.74	238.71	238.72	238.73	238.74
238.75	238.76	238.79	277.30	277.31	277.39	284.01
284.09	284.1	284.2	288.00	288.01	288.02	288.03
288.04	288.09	288.4	288.50	288.51	288.59	288.60
288.61	288.62	288.63	288.64	288.65	288.69	289.53
289.83	323.01	323.02	323.41	323.42	323.51	323.52
323.61	323.62	323.63	323.71	323.72	323.81	323.82
331.83	333.71	333.72	333.79	333.85	333.94	338.0
338.11	338.12	338.18	338.19	338.21	338.22	338.28
338.29	338.3	338.4	341.20	341.21	341.22	377.43
379.60	379.61	379.62	379.63	389.15	389.16	429.83
478.11	478.19	518.7	519.11	519.19	521.81	521.89
523.00	523.01	523.10	523.11	523.30	523.31	523.32
523.33	523.40	523.41	523.42	525.60	525.61	525.62
525.63	525.64	525.65	525.66	525.67	525.69	526.61
526.62	526.63	526.69	528.00	528.01	528.02	528.09
538	608.20 *	608.21 *	608.22 *	608.23 *	608.24 *	616.81 **
616.89 **	618.84 **	629.29 **	629.81 ** +	629.89 **	649.00 ** +	649.01 ** +
649.02 ** +	649.03 ** +	649.04 ** +	649.10 ** +	649.11 ** +	649.12 ** +	649.13 ** +
649.14 ** +	649.20 ** +	649.21 ** +	649.22 ** +	649.23 ** +	649.24 ** +	649.30 ** +
649.31 ** +	649.32 ** +	649.33 ** +	649.34 ** +	649.40 ** +	649.41 ** +	649.42 ** +
649.43 ** +	649.44 ** +	649.50 ** +	649.51 ** +	649.53 ** +	649.60 ** +	649.61 ** +
649.62 ** +	649.63 ** +	649.64 ** +	729.71	729.72	729.73	729.79
731.3	768.70 #	770.87 #	770.88 #	775.81 #	775.89 #	779.85 #
780.32	780.96	780.97	784.91	784.99	788.64	788.65
793.91	793.99	795.06 **	795.81	795.82	795.89	958.90
958.91	958.92	958.93	958.99	995.20	995.21	995.22
995.23	995.27	995.29	V18.51	V18.59	V26.34 *	V26.35 *
V26.39 *	V45.86	V58.30	V58.31	V58.32	V72.11	V72.19
V82.71	V82.79	V85.51	V85.52	V85.53	V85.54	V86.0 ** +
V86.1 ** +						

Restrictions
* Restricted to males only
** Restricted to females only
# Restricted to ages 0 thru 1 year
\+ Restricted to ages 10 thru 99

Inactive Codes
Effective for dates of service on or after October 1, 2006, the following ICD-9 diagnosis codes are no longer reimbursable:

238.7, 277.3, 284.0, 288.0, 323.0, 323.4, 323.5, 323.6, 323.7, 323.8, 333.7, 478.1, 519.1, 521.8, 523.0, 523.1, 523.3, 523.4, 528.0, 608.2, 616.8, 629.8, 775.8, 784.9, 793.9, 995.2, V18.5, V58.3, V72.1

Please see **ICD-9**, *page 3*

Code Description Revisions
The descriptions of the following ICD-9 diagnosis codes are revised:

255.10, 285.29, 323.1, 323.2, 323.9, 333.6, 345.40, 345.41, 345.50, 345.51, 345.80, 345.81, 389.11, 389.12, 389.14, 389.18, 403.00, 403.01, 403.10, 403.11, 403.90, 403.91, 404.00, 404.01, 404.02, 404.03, 404.10, 404.11, 404.12, 404.13, 404.90, 404.91, 404.92, 404.93, 524.21, 524.22, 524.23, 524.35, 600.00, 600.01, 600.20, 600.21, 600.90, 600.91, 780.31, 780.95, 790.93, 873.63, 873.73, 995.91, 995.92, 995.93, 995.94, V26.31, V26.32

Manual replacement pages reflecting these ICD-9 code updates will be included in a future *Medi-Cal Update.*

Synagis (Palivizumab) Billing Update

Effective for dates of service on or after September 1, 2006, providers may no longer bill for Synagis (palivizumab) using local codes X7441 (Synagis 50 mg) and X7439 (Synagis 100 mg).

In accordance with the provisions of *Business and Professions Code* (B&P Code), Section 4051, Pharmacy providers who purchase and then dispense Synagis directly to a physician's office or medical clinic for administration in the medical office or clinic setting, or to a Home Health Agency (HHA) for an approved in-home visit, which may include, but not be limited to, Synagis administration, may bill Medi-Cal through the CAL-POS online system, Computer Media Claims (CMC) or paper claims using the drug's National Drug Code (NDC). The physician's office or clinic will continue to bill Medi-Cal separately for the cost of administration of Synagis. The reimbursement for the cost of Synagis administration is included in an HHA visit, so it should not be billed separately.

All claims require an approved *Treatment Authorization Request* (TAR).

- Physicians who purchase Synagis directly for administration may continue to bill with CPT-4 code 90378 (Synagis 50 mg). The administration fee is included in the reimbursement for the drug.
- Providers who meet the criteria for billing Synagis using the drug's NDC must submit TARs to either the Southern Medi-Cal Pharmacy Office by fax at 1-800-869-4325, or the Northern Medi-Cal Pharmacy Office by fax at 1-800-829-4325, as determined by the provider's geographic location.
- Physician providers billing for Synagis with CPT-4 code 90378 must continue to submit TARs to the Los Angeles Medi-Cal Field Office by fax at 1-866-816-4377.

Ultrasound During Pregnancy Benefits Revised

Effective for dates of service on or after September 1, 2006, the diagnoses for which the following ultrasound CPT-4 codes may be reimbursed are expanded.

- CPT-4 code 76820 is to be reimbursed when billed with diagnosis code 658.03 (oligohydramnios) at term
- CPT-4 code 76821 is to be reimbursed when billed with diagnosis code 647.63 (anemia due to Parvovirus B19 infection)
- CPT-4 codes 76825 and 76826 are to be reimbursed when billed with diagnosis code 659.73 (abnormality in fetal heart rate or rhythm) during the 9th or 12th week of pregnancy

The American College of Obstetricians and Gynecologists (ACOG) and the American Medical Association (AMA) have confirmed that Doppler color flow mapping (CPT-4 code 93325) was valued into the Relative Value Units (RVU) for codes 76820 and 76821. Therefore CPT-4 code 93325 is not reimbursable on the same day, any provider, as codes 76820 or 76821.

Please see **Ultrasound**, *page 4*

Effective for dates of service on or after September 1, 2006, CPT-4 codes 76827 and 76828 (fetal Doppler echocardiography) have the following diagnosis and frequency restrictions.

- Reimbursement is limited to patients with diabetes mellitus (ICD-9 codes 648.00 – 648.03), congenital cardiovascular disorders (codes 648.50 – 648.53), abnormal glucose tolerance (codes 648.80 – 648.83), known or suspected fetal abnormality affecting management of mother (codes 655.00 – 655.93) and abnormality in fetal heart rate or rhythm (659.73).
  - – Reimbursement is limited to once in 180 days, to the same provider. Second and subsequent claims may be reimbursed with documentation justifying medical necessity.

The updated information is reflected on manual replacement pages preg early 5 and 8 (Part 2).

Frequency Restriction for Obstetric Panel

Effective for dates of service on or after September 1, 2006, reimbursement of CPT-4 code 80055 (obstetric panel) is restricted to once in nine months for the same provider. The provider may be reimbursed for a second or subsequent obstetric panel within the nine-month period if there is documentation to justify medical necessity or documentation of a different pregnancy.

The updated information is reflected on manual replacement pages path organ 6 (Part 2) and preg early 9 (Part 2).

Hospital Visit, Discharge Billing Policy Updated

Policy currently does not allow reimbursement for both a hospital visit (CPT-4 codes 99221 – 99223 and 99231 – 99233) and a hospital discharge service (codes 99238 – 99239) billed for the same date of service, for the same provider. The term "same provider" has been applied to include the same group provider number even when there is a different rendering provider.

Effective for dates of service on or after September 1, 2006, this policy is changing to allow reimbursement for both services when different rendering providers are billing using the same group provider number.

The updated information is reflected on manual replacement page eval 7 (Part 2).

Genetic Disease Counseling and Screening Services Billing Changes

Effective for dates of service on or after November 1, 2006, in compliance with HIPAA, the California Department of Health Services (CDHS) will allow only HCPCS Level II (national) codes when billing genetic disease counseling and screening services. HCPCS Level III (interim) codes and modifiers will no longer be reimbursable by Medi-Cal. More information will be available in future *Medi-Cal Updates*.

2006 CPT-4/HCPCS Updates: Implementation November 1, 2006

The 2006 updates to the *Current Procedural Terminology – 4th Edition* (CPT-4) and Healthcare Common Procedure Coding System (HCPCS) National Level II codes will be effective for Medi-Cal for dates of service on or after November 1, 2006. The affected codes are listed below. Only those codes representing current or future Medi-Cal benefits are included. Please refer to the 2006 CPT-4 and HCPCS Level II code books for complete descriptions of these codes. Specific policy, billing information and manual replacement pages reflecting these changes will be released in a future *Medi-Cal Update.*

CPT-4 Code Additions

Anesthesia
01965, 01966

Please see **HCPCS**, *page 5*

Surgery
15040, 15110, 15111, 15115, 15116, 15130, 15131, 15135, 15136, 15150, 15151, 15152, 15155 – 15157, 15170, 15171, 15175, 15176, 15300, 15301, 15320, 15321, 15330, 15331, 15335, 15336, 15340, 15341, 15360, 15361, 15365, 15366, 15420, 15421, 15430, 15431, 22010, 22015, 22523 – 22525, 28890, 32503, 32504, 33507, 33548, 33768, 33880, 33881, 33883, 33884, 33886, 33889, 33891, 33925, 33926, 36598, 37184 – 37188, 37718, 37722, 43770 – 43774, 43848, 43886 – 43888, 44180, 44186 – 44188, 44213, 44227, 45395, 45397, 45400, 45402, 45499, 45990, 46505, 46710, 46712, 50250, 50382, 50384, 50387, 50389, 50592, 51999, 53850, 57295, 58110, 61630, 61635, 61640 – 61642, 64650, 64653

Radiology
75956 – 75959, 76376, 76377, 77421 – 77423

Pathology and Laboratory
80195, 82271, 82272, 83631, 83695, 83700, 83701, 83704, 83900, 83907 – 83909, 83914, 86200, 86355, 86357, 86367, 86480, 86923, 86960, 87209, 87900, 88333, 88334, 89049

Medicine
90760 – 90768, 90779, 91022, 92626, 92627, 92630, 92633, 95865, 95866, 95873, 95874, 96101, 96116, 96118, 96401, 96402, 96409, 96411, 96413, 96415 – 96417, 96521 – 96523, 99143 – 99150, 99304 – 99310, 99324 – 99328, 99334 – 99337

HCPCS Level II Code Additions

Radiopharmaceuticals
A4641, A4642, A9500, A9502 – A9505, A9507, A9508, A9510, A9512, A9516, A9517, A9521, A9524, A9526, A9536 – A9567, A9600, A9605, A9698, A9699, C2634, C2635, C2637, Q9945 – Q9957

Surgery
C9724, C9725, S2068, S2075 – S2079, S2114, S2117

Injections and Drugs
A9535, C9225, J0132, J0133, J0135, J0278, J0480, J0795, J0881, J0882, J0885, J0886, J1162, J1265, J1451, J1640, J1675, J1751, J1752, J1945, J2278, J2325, J2425, J2503, J2504, J2805, J2850, J3285, J7306, J9175, J9225, J9264, Q0515, Q4079, S0145

Blood Factors
J7188, J7189

Cochlear Implant Lithium Batteries
L8623, L8624

Implantable Devices and Supplies
E0616, L8680 – L8689

Ventricular Assist Devices and Supplies
Q0480 – Q0505

CPT-4 Codes with Description Changes

Surgery
15000, 15001, 15100, 15101, 15120, 15121, 15200, 15240, 15260, 15400, 15401, 16020, 16025, 16030, 30130, 30140, 30801, 30930, 31520, 31525, 31526, 31530, 31531, 31535, 31536, 31540, 31541, 31560, 31561, 31570, 31571, 33502, 34833, 34834, 37209, 44202, 44310, 44320, 45119, 45540, 45550, 50688, 52647, 52648, 57421, 64613, 67901, 67902, 69725

Radiology
75900, 76012, 77412, 78608, 78609, 78811 – 78816

Pathology and Laboratory
82270, 83036, 83630, 83898, 83901, 84238, 86022, 86023, 86920 – 86922, 87534 – 87539, 87901 – 87904, 88175

Please see **HCPCS**, *page 6*

Vaccines
90713

Medicine
90657, 90658, 90870, 90940, 91020, 92506, 92507, 92520, 92568, 92569, 96405, 96406, 96420, 96422, 96423, 97024, 97811, 97813, 97814

HCPCS Level II Codes with Description Changes

Radiopharmaceuticals
A4641, A9528 – A9532

CPT-4 Code Deletions

Anesthesia
01964

Surgery
15342, 15343, 15350, 15351, 15810, 15811, 16010, 16015, 21493, 21494, 31585, 31586, 32520, 32522, 32525, 33918, 33919, 37720, 37730, 42325, 42326, 43638, 43639, 44200, 44201, 44239, 69410

Radiology
76375, 78160, 78162, 78170, 78172, 78455, 78990, 79900

Pathology and Laboratory
82273, 83715, 83716, 86064, 86379, 86585, 86587

Medicine
90780 – 90784, 90788, 90799, 90871, 90939, 92330, 92335, 92390 – 92393, 92325, 92396, 92510, 95858, 96100, 96115, 96117, 96400, 96408, 96410, 96412, 96414, 96520, 96530, 96545, 97020, 97504, 97520, 97703, 99052, 99054, 99141, 99142, 99261 – 99263, 99271 – 99275, 99301 – 99303, 99311 – 99313, 99321 – 99323, 99331 – 99333

HCPCS Level II Code Deletions

Radiopharmaceuticals
A4643 – A4647

Implantable Devices and Supplies
E0752, E0754, E0756 – E0759

California Temporary Codes
X1520, X6112, X6210, X6836, X7030, X7493, X7660, X7662

Family PACT
Planning • Access • Care • Treatment

Family PACT Clinical Services and Pharmacy Benefit Correction

The June 2006 *Medi-Cal Update* incorrectly listed the dosages and regimens of drugs used to treat sexually transmitted infections (STIs) and urinary tract infections (UTIs). The corrected information is as follows.

Metronidazole is a medication available for the treatment of Trichomoniasis and should not have appeared in the list of medications for the treatment of syphilis. The dosage and regimen of Ciprofloxacin for the treatment of urinary tract infections has been corrected.

Medication	Dosage Size	Regimens	Clinic Code	Notes
Trichomoniasis				
Metronidazole	500mg tabs	2g PO x 1	Z7610	recommended regimen
Urinary Tract Infection - Guidelines based on American Academy of Family Physicians Vol. 72/No. 3 (August 1, 2005)				
Ciprofloxacin	500mg tabs	500mg PO BID X 3 days	Z7610	

Please see **Family PACT**, *page 7*

Revised *Family PACT Policies, Procedures and Billing Instructions* (PPBI) manual pages will be issued in a future mailing to Family PACT providers. For more information about Family PACT, call the Telephone Service Center (TSC) at 1-800-541-5555 from 8 a.m. to 5 p.m. Monday through Friday, except holidays, or visit the Family PACT Web site at **www.familypact.org**.

Provider Orientation and Update Sessions

Medi-Cal providers seeking enrollment in the Family PACT (Planning, Access, Care and Treatment) Program are required to attend a Provider Orientation and Update Session. The dates for upcoming sessions are listed below.

Individual and group providers wishing to enroll must send a physician-owner to the session. Clinics wishing to enroll must send the medical director or clinician responsible for oversight of medical services rendered in connection with the Medi-Cal provider number.

Office staff members, such as clinic managers, billing supervisors and patient eligibility enrollment supervisors, are encouraged to attend but are not eligible to receive a *Certificate of Attendance*. Currently enrolled clinicians and staff are encouraged to attend to remain current with program policies and services. Medi-Cal laboratory and pharmacy providers are automatically eligible to participate in the Family PACT Program without attending an orientation session.

The session covers Family PACT provider enrollment and responsibilities; client eligibility and enrollment; special scope of client services and benefits; and provider resources and client education materials. This is not a billing seminar.

Please note the upcoming Provider Orientation and Update Sessions below.

Los Angeles	***San Diego***
August 14, 2006	**August 24, 2006**
Radisson Wilshire Plaza Hotel	Manchester Grand Hyatt
3515 Wilshire Boulevard	One Market Place
Los Angeles, CA 90010	San Diego, CA 92101

For a map and directions for these locations, go to the Family PACT Web site at **www.familypact.org**, click the appropriate session date under "Provider Orientations" and then click the "For directions: click here" link.

Registration
To register for an Orientation and Update Session, go to the Family PACT Web site at **www.familypact.org**, click "Registration" next to the appropriate date under "Provider Orientations" and print a copy of the registration form. Fill out the form and fax it to the Office of Family Planning, Attn: Darleen Kinner, at (916) 650-0468. If you do not have Internet access, you may request the registration form by calling 1-877-FAMPACT (1-877-326-7228).

Providers must supply the following when registering:

- Name of the Medi-Cal provider or facility
- Medi-Cal provider number
- Contact telephone number
- Anticipated number of people attending

Check-In
Check-in begins at 8 a.m. All orientation sessions start promptly at 8:30 a.m. and end by 4:30 p.m. At the session, providers must present the following:

- Medi-Cal provider number
- Medical license number
- Photo identification

Please see **Orientation**, *page 8*

Note: Individuals representing a clinic or physician group should use the clinic or group Medi-Cal provider number, not an individual provider number or license number.

Certificate of Attendance
Upon completion of the orientation session, each prospective new Family PACT medical provider is mailed a *Certificate of Attendance*. Providers should include the original copy of the *Certificate of Attendance* when submitting the Family PACT application and agreement forms (available at the session) to Provider Enrollment Services. Providers arriving late or leaving early will not be mailed a *Certificate of Attendance*. Currently enrolled Family PACT providers do not receive a certificate.

Contact Information
For more information about the Family PACT Program, please call 1-877-FAMPACT (1-877-326-7228) or visit the Family PACT Web site at **www.familypact.org**.

The Family PACT Program was established in January 1997 to expand access to comprehensive family planning services for low-income California residents.

Vision Care Cutoff Date Reminder for Providers of Vision Care Services Including Outpatient Clinics and Hospitals

On July 1, 2006, the California Department of Health Services (CDHS) discontinued the Vision CMC proprietary claims transaction format regardless of the date services were performed. Additionally, there is a new 50-3 *Treatment Authorization Request* (TAR) form that must be used to request prior authorization for medically necessary contact services and materials, low vision aids and non-Prison Industry Authority items for dates of service on or after July 1, 2006 regardless of media used to bill the claim.

To bill vision services with dates of service on or after July 1, 2006, providers have three options: paper claims, compliant electronic claims submission and electronic claims submission via the Internet (IPCS).

Paper Claims
The *Payment Request for Vision Care and Appliances* (45-1) claim form was end-dated July 1, 2006. The 45-1 can only be used to bill paper claims with dates of service **prior** to July 1, 2006. The *HCFA 1500* claim form must be used to bill paper claims with dates of service on or after July 1, 2006.

Electronic Claim Submission
Providers who successfully completed the *Medi-Cal Telecommunications Provider and Biller Application/Agreement* (DHS 6153) and test claims may bill electronically on the HIPAA-compliant 837 v.4010A1 transaction.

The ASC X12N 837 v.4010A1 Professional **Medical** Data Specifications **must** be used to submit vision claims with dates of service on or after July 1, 2006. For dates of service on or after July 1, 2006, the Medical Data Specifications (part of the *837 v.4010A1 Health Care Claim Companion Guide*) has been updated to include the required segments for vision claims. The ASC X12N 837 v.4010A1 Professional **Vision** Data Specifications must be used for claims with dates of service prior to July 1, 2006.

The companion guides are available on the Medi-Cal Web site (**www.medi-cal.ca.gov**). From the home page, click the "HIPAA" link and then the "ASC X12N Version 4010A1 Companion Guides and NCPDP Technical Specifications" link.

Electronic Claim Submission Using the Internet
Available for claims with dates of service on or after July 1, 2006, the HIPAA-compliant 837 Internet Professional Claim Submission (IPCS) Online Claim Form has been updated to give vision care providers an alternate method of submitting electronic claims through the Medi-Cal Web site. The online claim form has been updated to include new fields for billing vision services. The *Internet Professional Claim Submission (IPCS) User Guide* has been updated to reflect these changes.

Please see **HIPAA**, *page 9*

The IPCS system allows users to submit single vision service claims in real-time. The IPCS system does not perform online adjudication nor does it accept crossover claims. Claims submitted successfully receive a Claim Control Number (CCN) on the host response screen. If the IPCS system detects errors, the user will receive a "CLAIM REJECTED" message on the host response screen, and the claim can be edited to correct these errors before resubmitting. Submitted claims enter the daily batch cycle of the Medi-Cal claims processing system.

The IPCS system allows faster, more efficient data exchange between providers and CDHS.

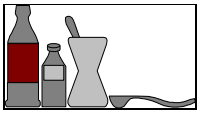
To use the IPCS system, providers must have both of the following:

- A *Medi-Cal Point of Service (POS) Network/Internet Agreement* form on file with CDHS for each provider number. If providers currently have valid forms on file, no additional updates are needed. Providers can download the form from the Medi-Cal Web site by clicking the "Forms" link on the home page, then clicking "Medi-Cal Point of Service (POS) Network/Internet Agreement." Providers should print the form, complete, sign and return it to Medi-Cal at the address shown on the form.
- A valid Computer Media Claims (CMC) submitter ID and password. To obtain or update your ID and password, complete the *Medi-Cal Telecommunications Provider and Biller Application/Agreement* (DHS 6153), which can be downloaded from the "Forms" page of the Medi-Cal Web site. Check the "Internet" box in the Real Time Submission Type section, check Medical/Allied Health (05) and enter 4010X098 where indicated in the ANSI X12N 837 Version section.

Note: Submitters with a current, valid CMC submitter ID must still submit the *Medi-Cal Telecommunications Provider and Biller Application/Agreement* to add the IPCS Internet options.

As of July 1, 2006, only professional medical and vision claims can be submitted using IPCS; Institutional claims cannot be submitted.

Additional Resources
For more information, in-state providers may call the Telephone Service Center (TSC) at 1-800-541-5555, 8 a.m. to 5 p.m., Monday through Friday. Border providers, software vendors and out-of-state billers who bill for in-state providers should call (916) 636-1200.



DRUG USE REVIEW
Educational Information

Use of Topical Calcineurin Inhibitors in the Medi-Cal Fee-For-Service (FFS) Population

On March 10, 2005 the Food and Drug Administration (FDA) issued a Public Health Advisory for the topical calcineurin inhibitors Pimecrolimus Cream (Elidel®) and Tacrolimus Ointment (Protopic®)[1].

On January 19, 2006, the FDA approved updates to the product labels and a *Patient Medication Guide* to be given to patients receiving pimecrolimus cream and tacrolimus ointment[2].

Pimecrolimus cream and tacrolimus ointment are topical immunosuppressant calcineurin inhibitors that are applied to the skin, and are the only approved drugs in this class.

The FDA's concerns are based on information from animal studies, case reports in small numbers of patients and on the mechanism of action of the drugs[1].

- Although a causal relationship has not been established, there have been rare cases of malignancy reported in patients being treated with topical calcineurin inhibitors
- Phase I animal data suggest that the risk of cancer increases with increased exposure to topical pimecrolimus or tacrolimus
- Long-term safety data of these drugs has not been established

Please see **Drug Use**, *page 10*

The FDA and the manufacturers recommend that healthcare providers, patients and caregivers consider the following[1,3,4].

- Use as ***second-line treatment*** in patients unresponsive to, or intolerant of, other treatments (e.g. topical corticosteroids)
- Indicated for ***short-term*** and ***intermittent*** treatment of mild to moderate atopic dermatitis (eczema)
- Avoid the use of pimecrolimus and tacrolimus in children younger than 2 years of age. The effect of these agents on the developing immune system in infants and children is not known
- Do not use in patients with a weakened or compromised immune system
- Use the minimum amount of pimecrolimus and tacrolimus needed to control the patient's symptoms

Topical pimecrolimus and tacrolimus are NOT indicated in children less than 2 years old and high-dose tacrolimus (0.1%) is NOT indicated in children less than 16 years of age[4].

For more information on label changes or to obtain Patient Medication Guides, visit: **www.fda.gov/bbs/topics/news/2006/NEW01299.html**

Medi-Cal conducted a retrospective study of beneficiaries with paid pharmacy claims for calcineurin inhibitors. Patients with at least one pharmacy paid claim for a calcineurin inhibitor between July 1, 2005 and December 31, 2005 were included in the analysis. The claims for these beneficiaries were analyzed for an 18-month lead-in period of January 1, 2004 through June 30, 2005 to determine if prescribing patterns were appropriate, including the trial/failure of another agent prior to initiation of treatment with a calcineurin inhibitor. It should be noted that only oral prednisone, oral methylprednisolone and topical corticosteroids were considered to determine previous therapies. Medi-Cal also recognizes that other agents (i.e. prednisolone, oral dexamethasone, Vitamin D analogs, etc.) can be used to treat eczema that were not included in this analysis.

There were a total of 714 continuously eligible beneficiaries identified who received a calcineurin inhibitor agent during the study period (July 1, 2005 through December 31, 2005).

- 22 percent of patients began treatment with a topical calcineurin inhibitor drug *before* trial/failure of a topical corticosteroid, oral prednisone, or oral methylprednisolone
- 15 percent of all patients with paid claims for topical calcineurin inhibitors were infants less than 2 years old
- 36 percent of all patients ages 2 through 15 with a paid claim for tacrolimus ointment were treated with the high dose (0.1 percent) strength

Medi-Cal is monitoring the utilization of all topical calcineurin inhibitors for appropriate use.

To report any unexpected adverse events associated with these agents, contact the FDA MedWatch program at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, HFD-410, 5600 Fishers Lane, Rockville, MD, 20857-9787; or online at **www.fda.gov/medwatch/report.htm**.

References

1. FDA Public Health Advisory Elidel (pimecrolimus) Cream and Protopic (tacrolimus) Ointment. Food and Drug Administration, March 10, 2005. **http://www.fda.gov/cder/drug/advisory/elidel_protopic.htm**
2. FDA News FDA Approves Updated Labeling with Boxed Warning and Medication Guide for Two Eczema Drugs, Elidel and Protopic. Food and Drug Administration, January 19, 2006. **http://www.fda.gov/bbs/topics/news/2006/NEW01299.html**
3. ELIDEL (Pimecrolimus, Novartis) Package Insert. **http://www.pharma.us.novartis.com/product/pi/pdf/elidle.pdf**
4. PROTOPIC (Tacrolimus, Astellas Pharma Inc.) Package Insert. **http://www.astellas.us/docs/protopic.pdf**

Medi-Cal List of Contract Drugs

The following provider manual sections have been updated: *Drugs: Contract Drugs List Part 1 – Prescription Drugs, Drugs: Contract Drugs List Part 2 – Over-the-Counter Drugs* and *Drugs: Contract Drugs List Part 4 – Therapeutic Classifications Drugs.*

Addition, effective May 24, 2006

Drug	**Size and/or Strength**
DECITABINE	
Injection	50 mg/vial

Addition, effective June 28, 2006

Drug	**Size and/or Strength**
*DARUNAVIR	
Tablets	300 mg
* Restricted to use as combination therapy in the treatment of Human Immunodeficiency Virus (HIV) infection.	

Addition, effective June 29, 2006

Drug	**Size and/or Strength**
DASATINIB	
Tablets	20 mg
	50 mg
	70 mg

Additions, effective August 1, 2006

Drug	**Size and/or Strength**	
INSULIN DETEMIR (rDNA origin)		
+ Injection	100 Units/cc	10 cc
ROSIGLITAZONE MALEATE/GLIMEPIRIDE		
+ Tablets	4 mg/1 mg	
	4 mg/2 mg	
	4 mg/4 mg	

Changes, effective August 1, 2006

Drug	**Size and/or Strength**
AMLODIPINE **BESYLATE**/BENAZEPRIL **HYDROCHLORIDE**	
+ Capsules	**2.5 mg – 10 mg**
	5 mg – 10 mg
	5 mg – 20 mg
	10 mg – 20 mg
	5 mg – 40 mg
	10 mg – 40 mg
OMEPRAZOLE/**SODIUM BICARBONATE**	
Powder packet	20 mg
	40 mg
Capsules	**20 mg**
	40 mg

+ Frequency of billing requirement

Please see **Contract Drugs**, *page 12*

Contract Drugs *(continued)*

Changes, effective August 1, 2006

Drug	**Size and/or Strength**
VALSARTAN/HYDROCHLOROTHIAZIDE	
+ Tablets	80 mg – 12.5 mg
	160 mg – 12.5 mg
	160 mg – 25 mg
	320 mg – 12.5 mg
	320 mg – 25 mg

Changes, effective September 1, 2006

Drug	**Size and/or Strength**
SIMVASTATIN	
+ Tablets	5 mg
	10 mg
	20 mg
	40 mg
	80 mg
(NDC Labeler Code 00006 [MERCK CO. INC])	

+ Frequency of billing requirement

Instructions for Manual Replacement Pages — Part 2

August 2006

General Medicine Bulletin 385

Remove and replace:	chemo 13/14 and 23/24 eval 7/8 inject list 5/6 and 17/18 medi non hcp 1/2 * medne 9/10 path organ 5/6
Remove:	preg early 5 thru 9
Insert:	preg early 5 thru 10
Remove and replace:	preg fetal 1/2 * tar and non cd7 1/2 *

DRUG USE REVIEW (DUR) MANUAL

Remove from the *Education* section:	36-31
Insert:	36-31 thru 33 *

* Pages updated due to ongoing provider manual revisions.